K003214

OCT 31 2000

510(k) Summary of Safety and Effectiveness

Trade Name:	Smith & Nephew Piston
Common Name:	Partial Ossicular Replacement Prosthesis
Classification Name:	Partial Ossicular Replacement Prosthesis (§ 874.3450)
Official Contact:	Jeffrey W. Cobb Group Director, Regulatory Affairs & Quality Smith & Nephew, Inc. ENT Division 2925 Appling Road Bartlett, TN 38133
Telephone:	(901) 373-0200
Fax:	(901) 373-0242
Date Prepared:	October 12, 2000

The Smith & Nephew Piston is substantially equivalent to the Schnuknecht Piston marketed by Smith & Nephew, Inc., ENT Division and the Fluoroplastic/Platinum Piston sold by Medtronic Xomed surgical Products, Inc.

Intended Use

The Smith & Nephew Piston has the same intended use as the Schnuknecht Piston and the Fluoroplastic/Platinum Piston: partial reconstruction of the ossicular chain that has lost its function due to disease, trauma, or congenital defect.

Material

The Smith & Nephew Piston differs from the predicate devices in the material used. The predicate devices use Stainless Steel (Schnuknecht) or Platinum (Fluoroplastic & Platinum) whereas the new Smith and Nephew Piston utilizes a Nitinol wire. All three products have a fluoroplastic shaft.

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Comparison Chart
Nitinol Piston vs. Schnuknect and Fluroplastic/Platinum Pistons

	Nitinol Piston (Smith & Nephew, Inc. ENT Division)	Schuknecht Piston (Smith & Nephew, Inc. ENT Division)	Fluroplastic and Platinum Pistons (Medtronic Xomed Surgical Products, Inc.)
Intended Use	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain	Partial Reconstruction of the Ossicular Chain
Loop Material	Nitinol	Stainless Steel	Platinum
Shaft Material	Fluoroplastic	Fluoroplastic	Fluoroplastic
Lengths	3.75 mm through 4.75 mm	3.00 mm through 5.75 mm	4.0 mm through 4.75 mm
Shaft Diameter	0.6 mm	0.6 mm	0.6 mm
How Supplied	Sterile	Sterile	Sterile

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2000

Mr. Jeffrey W. Cobb
Group Director, Regulatory Affairs & Quality
Smith & Nephew, Inc.
2925 Appling Road
Bartlett, TN 38133

Re: K003214
Trade Name: Smith & Nephew Piston
Regulatory Class: II
Product Code: 77 ETB
Dated: October 12, 2000
Received: October 13, 2000

Dear Mr. Cobb:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(K) NUMBER (IF KNOWN): K003214

DEVICE NAME: Smith & Nephew Piston

INDICATIONS FOR USE:

- Otosclerosis
- Congenital fixation of the stapes
- When previous remedial surgery has been unsuccessful for the treatment of hearing loss due to otosclerosis, and a significant conductive loss remains with good cochlear reserve.
- Chronic middle ear disease
- Trauma

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003214